The Honorable Richard A. Jones 1 2 3 4 5 6 7 UNITED STATES DISTRICT COURT 8 WESTERN DISTRICT OF WASHINGTON AT SEATTLE 9 E.S., by and through her parents, R.S. and J.S., 10 and JODI STERNOFF, both on their own NO. 2:17-cv-1609-RAJ 1 1 behalf, and on behalf of all similarly situated individuals, 12 SECOND AMENDED COMPLAINT Plaintiffs, 13 (CLASS ACTION) 14 v. 15 REGENCE BLUESHIELD; and CAMBIA HEALTH SOLUTIONS, INC., f/k/a THE 16 REGENCE GROUP, 17 Defendants. 18 INTRODUCTION 19 1. Hearing aids improve the health and quality of life for many people. 20 People who wear hearing aids do so because they find that otherwise, they are 21 significantly limited in their ability to work, participate in daily activities or to engage 22 socially. Hearing aids are rarely, if ever, sought unnecessarily because hearing aids are 23 not comfortable, affordable, or stylish. Indeed, the devices are highly stigmatized as 24 associated with old age and disability. Virtually everyone who obtains professionally 25 prescribed and fitted hearing aids is a person with a disability within the meaning of the 26

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER PLLC
3101 WESTERN AVENUE, SUITE 350
SEATTLE, WASHINGTON 98121
TEL. (206) 223-0303 FAX (206) 223-0246

12 13 14

16 17

15

18

19 20

21

22

23 24

25

26

Affordable Care Act's Section 1557, which incorporates, through Section 504, the definitions of disability found in the Americans with Disabilities Act, as amended in 2008.

- 2. Health plans issued by defendants Regence BlueShield and Cambia Health Solutions ("Regence") specifically exclude coverage for hearing aids except for cochlear implants. Plaintiffs initially alleged that this exclusion violates Section 1557 of the Affordable Care Act, which bars health insurers from discriminating based on disability. This Court granted defendants' motion to dismiss without leave to amend, reasoning that the exclusion is not discriminatory because it applies both to people whose hearing loss would qualify as a disability and to people without a hearing disability.
- 3. The Ninth Circuit reversed and remanded the case. According to the Ninth Circuit, the plaintiffs could state a case under Section 1557 by showing "that the exclusion is likely to predominately affect disabled persons," Schmitt v. Kaiser, 965 F.3d 945, 959, n. 8 (9th Cir. 2020), and that coverage for cochlear implants fails to meet the needs of most people with hearing loss. Id. at 959. For reasons set forth in this Second Amended Complaint, plaintiffs allege that the vast majority of people who wear professionally prescribed hearing aids are "disabled" under the pertinent federal definition, and that very few of those individuals with disabling hearing loss can have their needs met by treatment with cochlear implants.
- 4. The Ninth Circuit also recognized, in the alternative, that proxy discrimination exists where "the needs of hearing disabled persons differ from the needs of persons whose hearing is merely impaired such that the exclusion is likely to predominately affect disabled persons." Schmitt, 965 F.3d at 959, n. 8. For reasons set forth in this Second Amended Complaint, plaintiffs allege that the needs of the hearing disabled differ from the non-disabled such that Regence's exclusion predominately affects disabled persons.

- 5. Disability discrimination can also be pled through allegations showing a disparate impact on the disabled. Specifically, discrimination exists if the hearing disabled insureds on Regence's plans are impacted more significantly than the nondisabled such that the exclusion does not afford them meaning access to the benefits they require. For reasons set forth in this Second Amended Complaint, plaintiffs allege that Regene's exclusion of hearing aids has a disparate impact on its hearing disabled insureds.
- 6. Finally, discrimination under Section 1557 exists where discriminatory action is taken either intentionally, or with deliberate indifference of the consequences of the action on the disabled. For reasons set forth in this Second Amended Complaint, plaintiffs allege that Regene's exclusion of hearing aids violated its own internal evaluation process for determining whether a service or supply should be covered, and the exclusion was purposely drafted to override its internal process, a process that would have established the medical necessity and efficacy of hearing aids for its hearing disabled insureds. This was done solely to avoid the payment of claims, not for any scientific or medical reason, in violation of Section 1557.
- 7. Since this case was originally filed, the Washington Legislature has passed its own broad anti-discrimination statute that applies to health insurance plan design, RCW 48.43.0128. This statute prohibits all non-grandfathered health plans from discriminating on the basis of "present or predicted disability," or "health condition," in the design of benefits. *Id.* In 2020, the provision was expanded from individual and small group plans to all "non-grandfathered" health plans, with an effective date of June 11, 2020. *Id.* Under Washington law, an insured with any loss of hearing is disabled, and Regence's exclusion of hearing aids discriminates against those insureds. Accordingly, plaintiffs plead additional claims, including claims under Washington's Law Against Discrimination and Washington's Consumer Protection Act, due to

Regence's violations of RCW 48.43.0128. Declaratory and injunctive relief is also sought for Regence's violations of law.

II. PARTIES

- 8. *E.S.* Plaintiff E.S. is the ten-year-old daughter and dependent of R.S. and J.S. and resides in King County, Washington. E.S. is insured under a Regence BlueShield insured health plan. E.S. is diagnosed with disabling hearing loss and requires hearing aids.
- 9. *Jodi Sternoff.* Plaintiff Sternoff is an adult diagnosed with disabling hearing loss who resides in King County, Washington. Sternoff is insured under a Regence BlueShield insured health plan. She requires hearing aids.
- 10. Regence BlueShield. Regence BlueShield is an authorized health carrier based in King County and is engaged in the business of insurance in the State of Washington, including King County. Regence BlueShield is a Washington corporation that does business in the State of Washington, including King County. Regence BlueShield is a "health program or activity" that receives federal financial assistance that must comply with the Affordable Care Act, Section 1557.
- 11. Cambia Health Solutions, Inc., f/k/a The Regence Group. Cambia Health Solutions, Inc., f/k/a The Regence Group ("Cambia") is the nonprofit sole member and corporate owner of Regence BlueShield. Cambia is also the sole member and owner of other authorized health carriers engaged in the business of insurance in the State of Washington, including Regence BlueCross BlueShield of Oregon and BridgeSpan Health. Based upon information and belief, Cambia is a "health program or activity" that receives federal financial assistance that must comply with the Affordable Care Act, Section 1557.
- 12. Relationship between Regence BlueShield and Cambia. Regence BlueShield and Cambia are "alter egos." See McKinnon v. Blue Cross-Blue Shield of

1

Alabama, 691 F. Supp. 1314, 1319 (1988), aff'd, 874 F.2d 820 (1989). Regence BlueShield and the other authorized health carriers doing business in Washington that are wholly owned and/or managed by Cambia use the same or similar standard contracts for insured policies, and specifically, use the same or similar standard exclusions of coverage for hearing examinations, programs or treatment for hearing loss, the same standard definition of "medical necessity" and the same internal policies and procedures for determining when treatment for hearing loss is excluded. For the purpose of this Complaint, both Regence BlueShield and Cambia are referred to as a single defendant, "Regence."

III. JURISDICTION AND VENUE

- 13. This action arises under the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") § 1557, 42 U.S.C. § 18116.
- 14. Jurisdiction of this Court also arises pursuant to 28 U.S.C. §§ 1331, 1343. Jurisdiction for Plaintiffs' declaratory judgment, injunction, Consumer Protection Act and Washington Law Against Discrimination claims arises under 28 U.S.C. § 1367.
- 15. Venue is proper under 28 U.S.C. § 1391(b)(1) and (2), because, *inter alia*, a defendant resides or may be found in this district and a substantial part of the events giving rise to the claims occurred in King County, Washington.

IV. CLASS ALLEGATIONS

- 16. *Definition of Class*. The class consists of all individuals who:
 - (1) have been, are or will be insured under a health insurance plan that purports to exclude hearing aids and related services that has been, is or will be delivered, issued for delivery, or renewed by (a) Regence; (b) any affiliate of Regence; (c) predecessors or successors in interest of any of the foregoing; and (d) all subsidiaries or parent entities of any of the foregoing, at any time on or after October 30, 2014; and

- (2) have required, require or will require hearing aids and associated care, other than cochlear implants, for disabling hearing loss.
- 17. *Size of Class*. The class of Regence insureds who have required, require or will require hearing aids for disabling hearing loss, excluding cochlear implants, is so numerous that joinder of all members is impracticable.
- 18. Class Representatives E.S. and Sternoff. Named plaintiffs E.S. and Sternoff have been, and are presently, enrollees in a non-grandfathered Regence insured health plan in the State of Washington. Both have disabling hearing loss that requires hearing aids other than cochlear implants. Both are "qualified individuals with a disability" under the Affordable Care Act and Section 504 of the Rehabilitation Act, and both are "disabled" under Washington law. Both have required hearing aids to treat their hearing loss. Regence, under its pre-2020 policy and 2020 policies, denied both named Plaintiffs' requests for coverage, requiring them to pay out-of-pocket. Plaintiffs' claims are typical of the claims of the other members of the class. Plaintiff E.S., by and through her parents, and Plaintiff Sternoff, directly, will fairly and adequately represent the interests of the class.
- 19. Common Questions of Law and Fact. This action requires a determination of whether Regence's exclusion of hearing aids violated the requirements of the Affordable Care Act's § 1557 and discriminated against Plaintiffs on the basis of their disability. Adjudication of this issue will in turn determine whether Regence is liable under the Affordable Care Act for injunctive relief, including reprocessing claims, class wide damages and other relief. This action further requires a determination of whether Regence's exclusion of hearing aids violates the requirement of RCW 48.43.0128 and discriminates against Plaintiffs on the basis of their disability. Finally, this action requires a determination of whether Regence violated Washington's Consumer Protection Act and Law Against Discrimination by designing and applying a written

exclusion in violation of RCW 48.18.200(2), RCW 48.43.0128, and other Washington law. Finally, this action requires a uniform adjudication of whether Regence's conduct should be declared to be illegal, and Regence compelled by injunction to reprocess and pay claims that it denied in violation of law.

- 20. Regence Has Acted on Grounds Generally Applicable to the Class. Regence, by imposing a uniform exclusion on all coverage for hearing aids except for cochlear implants, has acted on grounds generally applicable to the class, rendering declaratory relief appropriate respecting the whole class. Certification is therefore proper under FRCP 23(b)(2).
- 21. Questions of Law and Fact Common to the Class Predominate Over Individual Issues. The claims of the individual class members are more efficiently adjudicated on a classwide basis. Any interest that individual members of the class may have in individually controlling the prosecution of separate actions is outweighed by the efficiency of the class action mechanism. Upon information and belief, there has been no class action suit filed against these defendants for the relief requested in this action. This action can be most efficiently prosecuted as a class action in the Western District of Washington, where Regence BlueShield has its principal place of business, does business, and where E.S. and Sternoff reside. Issues as to Regence's conduct in applying standard policies and practices towards all members of the class predominate over questions, if any, unique to members of the class. Certification is therefore additionally proper under FRCP 23(b)(3).
- 22. *Class Counsel*. Plaintiffs have retained experienced and competent class counsel.

V. FACTUAL BACKGROUND

A. Regence's Exclusion of Hearing Aids.

23. When this lawsuit was originally filed, Regence's insured health plans in Washington contained the following benefit exclusion:

We do not cover routine hearing examinations, programs or treatment for hearing loss, including but not limited to noncochlear hearing aids (externally worn or surgically implanted) and the surgery and services necessary to implant them.

Dkt. No. 12-1, p. 65 of 110. This exclusion, or one functionally identical, had been in place since at least October 30, 2014. In Regence's 2020 health plan issued to the named plaintiffs and members of the class, the exclusion is worded differently but has the same effect because "programs or treatment for hearing loss" are, in practical effect, coverage for "hearing aids":

SPECIFIC EXCLUSIONS

...

Hearing Aids and Other Hearing Devices

Hearing aids (externally worn or surgically implanted) and other hearing devices are excluded. This exclusion does not apply to cochlear implants.

. . .

Routine Hearing Examination

See Dkt. No. 32-1, pp. 31-33.

B. Hearing Loss, Hearing Aids and Cochlear Implants Defined.

1. Hearing Loss

24. Hearing involves a complex process by which sound waves are converted to vibrations that are transmitted through the eardrum to the middle-ear bones, then to the fluid-filled cochlea in the inner ear. The cochlea contains tiny hair cells that respond

to specific frequencies and emit microscopic electrical impulses to the auditory nerve, from which the brain decodes the sound. Hearing loss is the result of damage to one or more of those components.

- 25. A common preliminary screening for hearing loss is a pure-tone test, in which subjects are presented with tones at different frequencies (pitches), measured in Hertzes (Hz), at increasing volume, measured in decibels (dB). The subjects are asked to indicate when they hear those tones. The threshold loudness at which a tone becomes audible is recorded on an audiogram.
- 26. The critical metric from an audiogram is the average decibel threshold in the frequencies involving speech, which are the frequencies of 500, 1,000, 2,000 and 4,000 cycles per second, measured in Hertzes (Hz).
- 27. The generally accepted standard for normal hearing is a threshold of 25 dB. If the tones must be louder than 25dB to be audible, the subject has worse-than-normal hearing. An average decibel threshold greater than 25 dB in the speech frequencies is generally considered the point at which "hearing loss begins to impair communication in daily life." Lin *et al.*, *Hearing Loss Prevalence in the United States*, Archives of Internal Medicine Vol. 14, No. 20 at pp. 1831-32, Nov. 14 (2011).
- 28. The most common form of hearing loss is sensorineural hearing loss, in which the inner-ear hair cells are damaged. That damage is generally not correctible through surgery or medication, and can be mitigated only through hearing aids or, in extreme cases, cochlear implants. Plaintiff Sternoff is diagnosed with sensorineural hearing loss.
- 29. Conductive hearing loss occurs when damage to the outer or middle ear prevents sound from reaching the inner ear. Conductive hearing loss can be addressed with a bone-anchored hearing aid, which bypasses the damaged middle-ear structures and transmits sound directly to the cochlea and the hair cells. A bone-anchored hearing

aid is a different device than a "cochlear implant" and, as the name makes clear, is considered to be a type of hearing aid. Plaintiff E.S. is diagnosed with conductive hearing loss.

2. Hearing Aids

- 30. Washington state law defines "hearing instrument," as "any wearable prosthetic instrument or device designed for or represented as aiding, improving, compensating for, or correcting defective human hearing and any parts, attachments, or accessories of such an instrument or device," RCW 18.35.010(12). Hearing aids are "hearing instruments" within the meaning of Washington law.
- 31. The fitting and dispensing of hearing instruments are limited by law to licensed audiologists and licensed hearing-aid specialists. RCW 18.35.020. Audiologists must have doctoral-level education and experience. Hearing-aid specialists must have two years of college-level education plus supervised experience, RCW 18.35.040, and pass a state-mandated examination, RCW 18.35.070. Both licensed audiologists and hearing-aid specialists are defined as "hearing health care professionals." RCW 18.35.010(11). For purposes of this Second Amended Complaint, "hearing instrument" and "hearing aid" are used interchangeably to mean devices prescribed by these hearing health-care medical professionals in addition to the associated care in fitting, evaluating, and servicing.

3. Cochlear Implants

32. A cochlear implant is a mitigating measure for a limited class of people with severe to profound sensorineural hearing loss. A cochlear implant bypasses the damaged hair cells in the inner ear. It consists of an external microphone and processor that send electronic signals to an array of electrodes embedded in a filament that is

8

1 1

threaded into the cochlea. Those electrodes substitute for the damaged hair cells by sending electronic impulses directly to the auditory nerve, creating a sensation of sound.

33. A cochlear implant is only available to people with severe to profound hearing loss who cannot be adequately treated with hearing aids.

C. E.S.'s Need for Hearing Aids.

- 34. E.S. was born with a right unilateral grade 3 microtia with aural atresia. In other words, she was born without an outer ear or a properly formed middle ear on her right side. Her cochlea still functions, and her auditory nerve is intact, but she was born without an ear canal on her right side to allow sound to travel to her inner ear. Without a hearing aid, she is disabled under federal and state law.
- 35. As a result of this congenital birth defect, E.S. had maximum conductive hearing loss in her right ear and was incapable of receiving any benefit from a cochlear implant.
- 36. In 2016, while covered under a Regence policy, E.S. required a boneanchored hearing aid device to be implanted. The hearing aid was medically necessary and clinically appropriate for E.S.'s condition.
- 37. Regence denied coverage for the bone-anchored hearing aid device sought in 2016. It did so under the exclusion for hearing aids.
- 38. E.S.'s parents appealed the Regence denial of coverage for the bone-anchored hearing aid device and exhausted their administrative appeals in their attempt to obtain coverage. A reviewer concluded that the bone-anchored hearing aid system E.S. required was a bone conduction hearing aid and not a cochlear implant or prosthetic. The Sternoffs were required to pay for the bone-anchored hearing aid out-of-pocket.

D. Sternoff's Need for Hearing Aids.

39. Sternoff has moderate to severe hearing loss in her left ear and wears a "cross hearing aid" that transmits sound from her left side to her hearing right ear.

24

25

26

Without the hearing aid, she is disabled under federal and state law because her hearing loss substantially limits her ability to work, communicate, socialize and engage in other major life activities.

40. In 2016, Sternoff's request for coverage of her cross-hearing aid totaling \$4,100.00 was denied by Regence. The Sternoffs were required to pay for the hearing aid out-of-pocket.

E. Class-wide Allegations.

- 41. During the relevant time periods, E.S., Sternoff and members of the class have been insured in one or more Regence insured plans.
- 42. Plaintiffs E.S., Sternoff and other members of the class have been diagnosed with hearing loss, a physical impairment that limits a major life activity so substantially as to require medical treatment. As a result, E.S., Sternoff and other members of the class are "qualified individuals with a disability." *See* 28 C.F.R. § 39.103.
- 43. Plaintiffs E.S., Sternoff and other members of the class have required, require and/or will require hearing aids for their hearing loss, excluding treatment with cochlear implants.
- 44. Based on information and belief, the proposed class includes few if any individuals over the age of 65, since most, if not all, of Washington insured Regence enrollees lose their Regence coverage when they become eligible for Medicare.
- 45. The Regence health plans in which Plaintiffs are enrolled are "non-grandfathered health plans" as described in the Washington Insurance Code.
- 46. Regence's non-grandfathered insured health plans must comply with the requirements of RCW 48.43.0128.
- 47. The application of Regence's exclusion denies individuals with disabling hearing loss the benefits and health coverage available to other insureds, based on their disability.

25

26

48. As a direct result, Plaintiffs E.S., Sternoff and members of the class have paid out-of-pocket for medically necessary hearing aids and associated care for their hearing loss. Other class members have been forced to forgo needed hearing aids and associated treatment due to Regence's conduct.

49. Plaintiff E.S. has pursued her administrative appeal rights under her Regence health plan, to no avail. While any further administrative appeal would be futile, no such appeal is required before the claims alleged herein, including a § 1557 claim, may be brought. *See* 45 C.F.R. § 92.301(a); 81 Fed. Reg. 31441.

VI. CLAIMS FOR RELIEF¹

COUNT I - VIOLATION OF AFFORDABLE CARE ACT § 1557, 42 U.S.C. § 18116

- A. Regence Is Required to Comply with § 1557, and Plaintiffs and the Class Are Protected Under § 1557.
- 50. Regence is a "health program or activity" part of which receives federal financial assistance. 42 U.S.C. § 18116; 45 C.F.R. § 92.4. Regence is a "covered entity" under the Affordable Care Act, § 1557.
- 51. Regence provided assurances to the U.S. Department of Health and Human Services that it complies with the requirements of § 1557. *See* 45 C.F.R. § 92.5.
- 52. It also provided similar statements to its Washington insured enrollees, confirming that it complies with the requirements of § 1557.
- 53. Section 1557, 42 U.S.C. § 18116 provides that "an individual shall not, on the ground prohibited under ... section 504 of the Rehabilitation Act of 1973 ... be excluded from participation in, denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance...."

¹ Each claim for relief set forth below incorporates by reference all the allegations set forth in this Second Amended Complaint.

54. For purposes of § 1557, "disability" is defined and construed according to
Section 504 of the Rehabilitation Act, which, in turn "incorporates the definition of
disability in the Americans with Disabilities Act (ADA), as amended." 45 C.F.I
§ 92.102(c).

- 55. The ADA, 42 U.S.C. § 12101 *et seq.*, as amended in 2008, defines "disability" as "a physical or mental impairment that substantially limits one or more major life activities of such individual," 42 U.S.C. § 12102(1)(A) (emphasis added).
- 56. The applicable regulations state that the term "substantially limits" is to be construed "broadly," is not meant to be a "demanding standard," 29 C.F.R. § 1630.2(j)(1)(i).
- 57. "Major life activities" include, among other things, "hearing, communicating and working." 42 U.S.C. § 12102(2)(A).
- 58. The presence of a disability is to be assessed "without regard to the ameliorative effects of mitigating measures such as ... hearing aids or cochlear implants." 42 U.S.C. § 12102(4)(E)(i)(I).
- 59. Plaintiffs and the class, as defined, are "qualified persons with a disability" under both Section 504 and Section 1557 and are protected from discrimination under these provisions.

B. The Hearing Aid Exclusion Is a Proxy for Discrimination Against the Disabled.

- 1. The Hearing Aid Exclusion is a Proxy for Disability Discrimination Because Needs of the Disabled Are Not Met While the Needs of the Abled Are Met Under the Policy.
- 60. Discriminating against people who require hearing aids is a proxy for discrimination against people who have disabling hearing loss. Proxy discrimination exists where "the needs of hearing disabled persons differ from the needs of persons whose hearing is merely impaired such that the exclusion is likely to predominately

affect disabled persons." Schmitt v. Kaiser Found. Health Plan of Wash., 965 F.3d 945, 959, n. 8 (9th Cir. 2020).

- 61. The needs of hearing disabled persons differ significantly from the needs of persons whose hearing is merely impaired, but not disabling. The vast majority of Regence's hearing disabled insureds require hearing aids in order to perform major life activities. These are explicitly excluded under Regence's exclusion. In contrast, Regence's insureds with no hearing loss, or non-disabling hearing loss, are still able to perform, without any substantial limitations, all major life activities. As a result, Regence's exclusion has no, or little, effect on its non-disabled insureds.
- 62. Insureds with no hearing loss only require screenings or, at most, a diagnostic evaluation to determine if hearing loss exists. These services are covered by Regence under its policies. Hearing screening are covered as part of a physical examination, and hearing evaluations are covered as diagnostic examinations.
- 63. Insureds with hearing loss that does not substantially limit a major life activity also receive covered screenings and diagnostic testing under Regence's policies. Regence's exclusion of hearing aids has only a minimal impact on these non-disabled insureds. Even without a hearing aid, these insureds are not substantially limited in any major life activity.
- 64. In contrast, the needs of Regence's hearing disabled insureds are materially different, and profoundly impacted by Regence's exclusion. Specifically, the exclusion of hearing aids has a severe impact on Regence's insureds who are hearing disabled. The vast majority of these insureds require hearing aids in order to engage in major life activities, *e.g.*, working, going to school, socializing, or communicating. The wholesale exclusion of hearing aids by Regence profoundly effects the lives of these insureds.
- 65. As more specifically alleged below, (1) the needs of the non-disabled are met under the Regence's policy because hearing screenings and diagnostic hearing

testing, the only services required by the non-hearing disabled are covered by Regence, while (2) hearing aids, the benefit required by the vast majority of Regence's hearing disabled are excluded. The needs of hearing disabled persons therefore differ significantly from the needs of persons whose hearing is merely impaired, but not disabling, and Regence discriminates against its insureds who are hearing disabled.

- a. The Hearing-Related Medical Care Required by Non-Disabled Insureds Is Met by Regence Because Hearing Screenings and Diagnostic Hearing Testing Are Covered Services.
- 66. Hearing screenings, hearing examinations and initial hearing diagnostic testing are all designed to determine whether a loss of hearing has occurred. Screening and routine hearing examinations are "pass/fail" tests either the test identifies a potential problem with an individual's ability to hear, or it does not. If the screening or examination identifies a potential problem, then the individual is referred to a provider for a diagnostic hearing evaluation. A diagnostic hearing evaluation is then administered to further understand the nature, extent, and source of the deficit.
- 67. If a hearing screening, hearing examination or initial hearing diagnostic test determines that there is no hearing loss, then there is no indicated medical treatment necessary beyond the screening itself. For insureds with hearing loss that does not limit life activities, hearing aids are not medically indicted, and are not prescribed by medical providers. In addition to not being prescribed by a provider, these individuals do not seek and/or wear hearing aids due to the stigma, aesthetics, discomfort, inconvenience and expense of such devises. *See www.merckmanuals.com/home/ear,-nose,-and-throat-disorders/hearing-loss-and-deafness/management-of-hearing-loss* ("Many people are reluctant to wear hearing aids because of cost, comfort issues, and for some, social stigma.").

- 68. Notwithstanding Regence's purported exclusion of "routine hearing examinations," Regence, in fact, pays for screening examinations designed to determine whether an insured's hearing is functioning properly. It has paid for these hearing screening services from at least October 30, 2014, to the present. Payment for hearing screening and examinations is paid for by Regence under the benefit for a physical examination, as follows:
- (a) Regence provides full coverage for physical examinations. Dkt. No. 32-1, p. 26 of 91. These physical examinations include, as part of a bundle of covered services, an evaluation of the physical structures of the ear and screening to determine whether there is potential hearing loss. Regence makes no effort to exclude these services and, in fact, pays for these services as part of a covered physical examination.
- (b) In a routine physical, the examination of the ear involves the physician examining both ears using an otoscopic to determine and evaluate potential hearing loss. The physical exam also includes at least one of a number of evaluative hearing tests, including the tuning fork test, scratch test, whispered voice test, and/or use of a handheld audiometric devise. All of these are common hearing tests.
- (c) An evaluation of the ability of a patient to hear is, in fact, one of the required elements of a physical examination. CMS's 1997 "Content and Documentation Requirements" for physicians conducting a "general multi-system examination" a physical requires an "otoscopic exam of external auditory canals and tympanic membranes including pneumo-otoscopy with notation of mobility of membranes" and "[a]ssessment of hearing with tuning forks and clinical speech reception thresholds (eg, whispered voice, finger rub)." See www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf. See also Clinical Methods, 3rd Edition, Table 4.3 (1990) available from the National Institutes of Health at www.ncbi.nlm.nih.gov/books/NBK361/table/A253/?report=objectonly

25

26

(steps of physical exam include "examin[ing] the pinnae and periauricular tissues, Test auditory acuity, perform Weber and Rinne maneuvers ... observe the auditory canals and tympani.").

- (d) As a result, insureds with no hearing loss, or hearing loss that is not disabling, are provided with covered hearing screening services to evaluate hearing loss as part of a physical, which is covered at 100% by Regence.
- 69. In addition to having access to hearing loss screenings or examinations covered as part of a physical, insureds with no hearing loss, or hearing loss that does not limit life activities, are able to access free hearing screening services. These services are provided free of charge in schools, community centers, and social service agencies. See RCW 28A.210.020; WAC 246-760 (free hearing screening required in schools); www.sphsc.washington.edu/hearing-evaluations (University of Washington Speech Hearing Sciences provides free evaluations) (last visited 2/14/22); www.nlfoundation.org/services/health-screenings/ (Northwest Lions Foundation Free Hearing Screening) (last visited 2/15/22). In addition, providers will screen hearing free of charge. See, e.g., www.hearinglife.com (last visited 2/14/22). Finally, app-based hearing tests are available free of charge to screen for hearing loss. See www.mayoclinic.org/diseases-conditions/hearing-loss/diagnosis-treatment/drc-20373077 ("Tests to diagnosis hearing loss may include: ... Mobile apps are available that you can use by yourself on your tablet to screen for moderate hearing loss.") (last visited 2/15/22).
- 70. Not only do Regence's insureds with no hearing loss, or non-disabling hearing loss, have access to screening examinations, they also have access to diagnostic examinations. A diagnostic hearing examination occurs if an individual "fails" a screening examination. If a routine hearing examination identifies that an individual

1 1

potentially has a hearing deficit, then the provider will refer the patient for a diagnostic examination to determine the nature and extent of the deficit.

- 71. A diagnostic hearing examination is not a "routine hearing examination." It is therefore not excluded under Regence's policy as a "routine hearing examination." A diagnostic hearing examination is not a "hearing aid" excluded under the 2020 policy exclusion. Nor is it excluded as a "program[] or treatment for hearing loss" under the pre-2020 policies because, like all diagnostic interventions, the goal of the service is not to treat hearing loss, but to diagnose, *i.e.* identify whether a condition exists and the extent of any issue. *See* Stedman's Medical Dictionary 531 (defining "diagnosis" as "[t]he determination of the nature of a disease, injury or congenital defect"). This diagnosis is necessary, for example, to determine if the insured is a candidate for a cochlear impact, a covered service.
- 72. "Diagnostic Procedures" have, at all relevant times, been covered services under Regence's policies. *See, e.g.*, Dkt. 32-1, p. 27 of 91. Regence, since at least October 30, 2014, has paid for services received by its insureds for diagnostic hearing examinations notwithstanding its exclusions for "routine hearing examinations" and "programs or treatment for hearing loss."
- 73. As a result, insureds with no hearing loss or non-disabling hearing loss have insurance coverage from Regence for all the services that they may need: hearing screening, examinations and diagnostic testing. Regence's exclusions have no effect on these insureds.

b. The Hearing Disabled Insureds Are Targeted by the Exclusion.

74. In contrast, insureds with disabling hearing loss who require medical services after diagnosis are profoundly affected by Regence's exclusion of hearing aids. With the singular exception of cochlear implants, the services that are designed to treat or ameliorate disabling hearing loss are excluded.

75. Insureds with hearing loss that substantially limits a major life activity require medical interventions beyond screening or diagnostics. Specifically, these insureds require hearing aids (either amplification or bone-anchored) or, for a small minority, cochlear implants. See www.merckmanuals.com/home/ear,-nose,-and-throat-disorders/hearing-loss-and-deafness/management-of-hearing-loss (last visited 2/15/22). These disabled insureds also require follow-up care such as periodic adjustments to hearing aids and associated care which are also excluded by Regence under its hearing aid exclusion.

76. Insureds with hearing loss that does not substantially affect a major life activity are only minimally impacted by Regence's exclusion of hearing aids. Even without access to hearing aids, these insureds are still able to work, socialize, communicate, go to school, and otherwise interact with others. In contrast, insureds with hearing loss that substantially impacts a major life activity have no covered access to the health care that they require to work, socialize, go to school, or otherwise interact with others. As a result, Regence's exclusion predominately and profoundly effects those with disabling hearing loss and has no or a minimal impact on insureds with no or nondisabling hearing loss.

77. The inclusion of coverage for cochlear implants does not change this result. Cochlear implants are only appropriate for individuals with profound or severe hearing loss, which is only about 5.5% of the total population of individuals with bilateral hearing loss, and less than 20% of the total subpopulation of individuals with bilateral moderate, severe, and profound hearing loss. Dkt. No. 32-2 at 2; Dkt. No. 41 at 16. Regence's coverage for cochlear implants meets the needs of only a small minority of insureds.

78. For more than 80% of the hearing disabled, the appropriate treatment for their hearing loss is not a cochlear implant but a hearing aid. Hearing aids and associated

25

26

services are wholly excluded under Regence's health plans from 2020 and earlier. Even today, Regence continues to design and market health plans with the same or similar exclusion.

- 2. The Hearing Loss Exclusion Is a Proxy for Disability Discrimination Because It Statistically Predominately Affects the Disabled.
- 79. Regence's Hearing Loss Exclusion is also a proxy for discrimination against its hearing disabled insureds because it statistically affects those insureds to a far greater degree than non-disabled insureds.
- 80. The total population of Regence's insureds can be categorized into five groups based on the relative ability to hear: (1) those with no hearing loss, (2) those with mild hearing loss that does not render them disabled, (3) those with mild hearing loss that substantially interferes with a major life activity, (4) those with moderate hearing loss, (5) those with severe hearing loss, and (5) those with profound hearing loss. Those with moderate, severe, and profound hearing loss are necessarily disabled because the inability to hear a person across a quiet room and/or hear in a normal conversation substantially limits an individual's ability to work, go to school, socialize or otherwise life activity. See also www.cdc.gov/ncbddd/ engage in major hearingloss/parentsguide/understanding/understandinghearingloss.html (CDC's definition of moderate hearing loss: "a person with moderate hearing loss may hear almost no speech when another person is talking at a normal level.") (last visited 2/18/22). Those with mild hearing loss are also disabled if the defect is significant enough to substantially impair a major life activity.
- 81. Regence's insureds with no hearing loss are not impacted at all by the exclusion of hearing aids. These insureds have access to hearing screenings and diagnostic hearing examinations under Regence's policies. Hearing screenings are paid

for by Regence under the benefit for physical examinations, and diagnostic hearing tests are specifically covered as diagnostic procedures. These insureds also have access to free hearing screening at schools, community centers, businesses and through on-line apps. Likewise, Regence's insureds with non-disabling hearing loss have access to these same services.

- 82. On the other end of the spectrum, certain of Regence's insureds with severe or profound hearing loss have access to cochlear implants. However, the number of these individuals is small: 5.5% of the total population with hearing loss, and less than 20% of the population with moderate or greater hearing loss. Dkt. No. 32-2 at 2; Dkt. No. 41 at 16. Cochlear implants do not "serve the needs of most individuals with hearing disability." *Schmitt*, 965 F.3d at 959.
- 83. The impact of Regence's exclusion of hearing aids is, therefore, on those insureds who seek hearing aids. The vast majority of these individuals are disabled.
- 84. The Center for Disease Control and Prevention conducts a National Health and Nutrition Examination Survey ("NHANES"). www.cdc.gov/nchs/nhanes/index.htm (last visited 2/18/22). This survey is the gold standard for determining the prevalence of multiple conditions in the United States, including hearing loss and use of hearing aids. The data collected by the CDC is used by academics and researchers in the field. See e.g. Dkt. No. 32-2 ("Prevalence of Hearing Loss by Severity in the United States" is based on NHANES data).
- 85. Data from the demographics and audiometry questionnaire of NHANES were analyzed by Frank R. Lin, M.D., PhD, from the Department of Otolaryngology and Neck Surgery at Johns Hopkins University School of Medicine. Dr. Lin is the co-author of "Prevalence of Hearing Loss by Severity in the United States" at Dkt. No. 32-2.
- 86. Dr. Lin used data from the demographics and audiometry questionnaire of NHANES for the 2001-12 and 2015-18 cycles. The data is collected in such a way that

1 1

it can be determined how many people with hearing aids between the ages of 18 and 64 are disabled, as follows:

- (a) In NHANES, "disabling hearing" is defined in two ways: (1) Participants self-report of having moderate loss or more without a hearing aid (*i.e.*, moderate hearing trouble, a lot of trouble, or deaf). For data from 2001-2004, "moderate hearing trouble" was a not a response option so disabling hearing loss was defined as a "lot of trouble" or "deaf." (2) Participants reported not being able to hear and understand a person speaking in a normal voice across a quiet room without a hearing aid. This definition closely tracks the ADA definition of disability.
- (b) In NHANES 2001-12, a hearing aid user was defined as having worn a hearing aid in the past 12 months (2001-04), having worn a hearing aid at least 5 hours a week (2005-10), or having worn a hearing aid in the past 12 months (2011-12). In NHANES 2015-18, a hearing aid user was defined as having worn a hearing aid in the past 12 months (2015-16) or having worn a hearing aid in the past 2 weeks (2017-18).
- (c) The data indicates that, of the people who use a hearing aid, 75% had disabling hearing loss without the assistance of the aid during the 2001-2012 NHANES survey cycle. For the 2015-2018 NHANES survey cycle, 72% of the individuals had disabling hearing loss without the assistance of the aid. This data was screened to exclude individuals over the age of 64, as those individuals would be covered by Medicare rather than under a Regence policy. (If this data was included, the numbers would have been higher given that hearing worsens with age.)
- 87. As a result, from a purely statistical standpoint, the exclusion of hearing aids is a form of proxy discrimination since the "fit" between the exclusion and disabling hearing loss is "sufficiently close" to make a discriminatory inference plausible given that the exclusion of hearing aids "primarily affects disabled persons." *See Schmitt*, 965 F.3d at 958-959.

C. The Hearing Loss Exclusion Has a Disparate Impact Against Disabled Insureds.

- 88. Separate from a proxy analysis, an insurer may also discriminate though exclusions that have a disparate impact against those with a disability. *Doe v. CVS Pharm., Inc.,* 982 F.3d 1204 (9th Cir. 2020). *See also Payan v. L.A. Cmty. College Dist,* 11 F.4th 729 (9th Cir. 2021).
- 89. The nature of the benefit at issue in this case is access to medical treatment necessary to address the needs of Regence's insureds who are hearing disabled. For the vast majority of these disabled insureds, a hearing aid and associated care is the critical benefit they require to ameliorate their medical condition. It is also the benefit excluded by Regence in its design of benefits. Put simply, Regence discriminates against them by eliminating various aspects of hearing care that is critical to their health.
- 90. Regence's disabled insureds are denied meaningful access to the coverage that they require to treat their disability hearing aids under Regence's discriminatory design of its health benefits policy. Regence's policies have, at all relevant times, excluded coverage for hearing aids and associated care. Regence, however, explicitly provides coverage for all other forms of medically necessary prosthetics. Dkt. No. 32-1, p. 13 of 91; p. 45 of 91. Under Washington law, a hearing aid is a prosthetic device. RCW 18.35.010(12). Yet, it is excluded by Regence in its policies, impacting its hearing disabled insureds in a targeted and unique way. The hearing aid exclusion does not uniformly affect all Regence's insureds; rather, it only effects those hearing disabled insureds who need hearing aids, a prosthetic that would be covered "but for" Regence's benefit design that excludes them.
- 91. Regence's decision to draft and enforce policy terms that exclude hearing aids for its hearing disabled insureds is an inherently intentional act. At minimum, the exclusion of hearing aids a proven medical intervention to treat the hearing disabled was undertaken with deliberate indifference to the needs of this population.

24

25

26

92. Regence's exclusion of hearing aids disproportionately affects people with hearing disabilities who require, in order to overcome limitations to substantial life activities, access to hearing aids. The exclusion has the effect of systematically excluding people with disabling hearing loss from obtaining the health insurance benefits that they require.

D. Regence Intentionally Discriminated Against Disabled Insureds.

- Regence utilizes an internal process to evaluate whether a medical service should be covered or excluded. The review, termed a "technology assessment process," examines five elements: (1) the technology must have final approval from the appropriate government regulatory bodies; (2) the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; (3) the technology must improve the net health outcomes; (4) the technology must be as beneficial as any established alternatives; and (5) the improvement must be attainable outside https://blue.regence.com of investigational See settings. <u>/trgmedpol/intro/index.html</u> (last visited 2/17/22). If a service or supply meets these requirements, then it is eligible for coverage unless the policy specifically provides otherwise. Id.
- 94. Hearing aids for the hearing disabled meet all five requirements of Regence's technology assessment process. Hearing aids to treat the hearing disabled have final approval from the government, the scientific evidence uniformly and unequivocally supports their use to ameliorate hearing loss, they improve net heath outcomes, they are the most beneficial intervention for the vast majority of the hearing disabled and the benefit is not limited to investigational settings.
- 95. Despite the fact that hearing aids would be eligible for coverage under Regence's own technology review process, Regence made the conscious and intentional decision to draft and enforce a specific exclusion that would override its process for

determining medically appropriate health care. The drafting and enforcement of a specific exclusion therefore led Regence to deny coverage for a service or supply that would otherwise be covered as medically appropriate under its own review process. *See* https://blue.regence.com/trgmedpol/intro/index.html ("To the extend there are any conflicts between medical policy guidelines and applicable contract language, the contract language takes precedence.") (last visited 2/17/22).

- 96. Regence's decision to exclude hearing aids was not based upon medical necessity or effectiveness of the intervention. Regence never concluded that hearing aids were not clinically effective or not medically necessary. Rather, Regence decided to exclude hearing aids for one reason: to avoid paying medical claims for hearing aids. Because those claims could not be avoided due to the lack of cost-effectiveness or medical necessity under its medical review process, Regence decided to impose a blanket exclusion on the service.
- 97. Exclusions related to conditions protected by the anti-discrimination protections of the law are only proper if "[s]cientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557." See 81 Fed. Reg. 31, 405. Regence had no scientific or medical reason to deny hearing aids to the hearing disabled. No medical review concluded that hearing aids were not effective, warranted and necessary for its hearing disabled insureds.
- 98. This discriminatory decision directly resulted in Regence retaining money that it would otherwise would have been required to pay to cover medically necessary and appropriate medical services and equipment for disabled insureds. Regence made this calculus as part of its underwriting process and decided that its desire to retain money outweighed the medical needs of its insureds with disabling hearing loss.

25

26

99. As a result, the design and administration of the exclusion on hearing aids was an intentional choice or, at the very least, the result of deliberate indifference to the effect it would have on its insureds with disabling hearing loss.

COUNT II – VIOLATIONS OF WASHINGTON LAW AGAINST DISCRIMINATION

- RCW 48.43.0128 provides that a health carrier such as Regence is prohibited from "[i]n its benefit design or implementation of its benefit design, discriminat[ing] against individuals because of ... present or predicted disability. ... " A violation of RCW 48.43.0128 is "unfair discrimination" under RCW 48.30.300, and therefore subject to Washington's Law Against Discrimination.
- 101. The definition of "disability" under Washington law is far broader than the ADA definition. See RCW 49.60.040(7)(a) ("Disability means the presence of a sensory, mental or physical impairment that: (i) [i]s medically cognizable or diagnosable; or (ii) [e]xists as a record or history; or (iii) [i]s perceived to exist whether or not it exists in fact."). Under Washington law, a diagnosis of hearing loss is always a "disability" because it is a physiological disorder or condition that affects the body systems listed in RCW 49.60.040(7)(c)(i). See Taylor v. Burlington N. R.R. Holdings, Inc., 193 Wn.2d 611, 617, 444 P.3d 606 (2019).
- Regence has designed a benefit plan that provides coverage for the hearing-related needs of insureds with no hearing loss (i.e., screenings and diagnostic exams), but excludes coverage of the medically necessary care for the vast majority of its insureds with hearing loss. For insureds with hearing loss, the only coverage available to treat their medical condition is a cochlear implant. This coverage would only provide benefits to about 5.5% of the total population of individuals with bilateral hearing loss. Dkt. No. 32-2, p. 2. The exclusion of hearing aids is a benefit design that uniquely targets those with hearing loss.

SIRIANNI YOUTZ SPOONEMORE HAMBURGER PLLC 3101 Western Avenue, Suite 350 SEATTLE, WASHINGTON 98121

Tel. (206) 223-0303 Fax (206) 223-0246

23

24

25

26

103. Plaintiffs and the class are entitled to remedies under the Washington Law Against Discrimination, including injunctive relief requiring reprocessing of claims, actual damages, attorney fees, and all other appropriate remedies permitted under RCW 49.60.030(2).

COUNT III - CONSUMER PROTECTION ACT VIOLATIONS

- Regence's exclusion of hearing aids in its benefit design constitutes a violation of Washington's Consumer Protection Act, RCW 19.86 et seq. All of the elements of a CPA claim are present here: (1) an unfair or deceptive act or practice (2) occurring in trade or commerce (3) that affects the public interest, (4) injury to property, and (5) causation.
- Regence's exclusion of hearing aids is an unfair or deceptive act or practice because it unlawfully discriminates against its insureds with hearing loss, a disability under Washington law. Specifically, Regence violated RCW 48.43.0128 because it drafted and implemented a benefit design that "discriminates against individuals because of their ... present or predicted disability ... or other health conditions." The exclusion of hearing aids only affects those with hearing loss, which is a disability under RCW 49.60.040(7)(a). This conduct is defined as "unfair discrimination" under RCW 48.30.300. It is therefore a per se violation of the CPA. Regence's exclusion of hearing aids also constitutes an unfair or deceptive act or practice because discrimination against the disabled, including discrimination in the design of health benefits, is in violation of the public interest.
- 106. Regence is engaged in the business of insurance, which is involved in trade and commerce that affects the public interest. RCW 48.01.030.
- 107. Plaintiffs and the class have sustained injuries to their property that were caused by Regence's exclusion, including having to pay for hearing aids out of pocket when insurance coverage should have been provided.

17

18

19

20

21

22

23

24

25

26

108. Plaintiffs and the class are entitled to damages, treble damages and attorney's fees and costs because of Regence's violations of the CPA.

COUNT IV - DECLARATORY RELIEF

- 109. RCW 48.43.0128 renders Regence's exclusion of hearing aids null and void, since it is a form of benefit design discrimination targeted at disabled individuals with hearing loss. Specifically, since the plaintiffs are disabled under Washington law, and Regence's health plans are subject to RCW 48.43.0128, the exclusion discriminates against Plaintiffs since Plaintiffs' disability is a "substantial factor" in causing the exclusion of coverage. See Fell v. Spokane Transit Auth., 128 Wn.2d 618, 637, 911 P.2d 1319 (1996).
- 110. Plaintiffs and the class are entitled to declaratory relief as to the meaning and effect of RCW48.43.0128 and Washington law on their Regence health care coverage.

COUNT V - INJUNCTIVE RELIEF

111. Regence's failure to comply with the law also justifies entry of an injunction prohibiting Regence from further violations of the law and requiring Regence to solicit and process claims for hearing aids that were not submitted for payment due to its policy, and reprocess and pay claims that were wrongfully denied under its policies.

VII. DEMAND FOR RELIEF

WHEREFORE, Plaintiffs request that this Court:

- 1. Certify this case as a class action; designate the named Plaintiffs as class representatives; and designate SIRIANNI YOUTZ SPOONEMORE HAMBURGER, Eleanor Hamburger, Richard E. Spoonemore, and John Waldo (of counsel) as class counsel;
- 2. Enter judgment on behalf of the Plaintiffs and the class due to Regence's discrimination on the basis of disability under both Section 1557 and RCW 48.43.0128;

- 3. Declare that Regence may not apply the hearing aid exclusion, and that its past exclusions of hearing aids was unlawful discrimination;
- 4. Enjoin Regence from applying the hearing aid exclusion and/or other violations of the Affordable Care Act now and in the future;
 - 5. Require Regence to reprocess and pay claims wrongfully denied;
- 6. Enter judgment in favor of Plaintiffs and the class for damages in an amount to be proven at trial due to Regence's violation of Section 1557 of the Affordable Care Act and RCW 48.43.0128 of the Washington Insurance Code, and violations of the WLAD and CPA, including actual damages, treble damages, costs and attorney's fees; and
 - 7. Award such other relief as is just and proper.

DATED: February 22, 2022.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER PLLC

/s/ Richard E. Spoonemore

Richard E. Spoonemore (WSBA #21833) Eleanor Hamburger (WSBA #26478) 3101 Western Avenue, Suite 350 Seattle, WA 98121 Tel. (206) 223-0303; Fax (206) 223-0246 Email: ehamburger@sylaw.com rspoonemore@sylaw.com

Of Counsel:

<u>/s/ John F. Waldo</u> John F. Waldo, *Pro Hac Vice*

Law Office of John F. Waldo 2108 McDuffie St. Houston, TX 77019 Tel. (206) 849-5009 Email: johnfwaldo@hotmail.com

Attorneys for Plaintiffs